K121023

MAY 3 1 2012

510(k) SUMMARY

[as required by section 807.92(c)]

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

General Information

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Date Prepared:	May 1, 2012

Device Name

Trade Name:	IMI Spectrum V.0
Common Name(s):	Picture Archiving and Communications System Image Processing System

Classification

Regulation:	21 CFR §892.2050
Class:	Class II
Product Code:	LLZ

Predicate Device

Vitrea, Version 4.0 Medical Image Processing Software	K071331	Vital Images, Inc.

Device Description

IMI Spectrum V.0 is a medical diagnostic device that allows the processing, review, and analysis of multi-dimensional digital images acquired from a variety of imaging devices.

The IMI Spectrum V.0 contains all the required hardware and software to provide an interactive 3D and 2D views of diagnostic CT images. The views include both inner and outer surface 3D volume rendered images as well as orthogonal and multiplanar reformatted 2D images. This ability to view the dataset in different perspectives from which it was acquired is performed by first transferring DICOM images from the CT scanners to the IMI Spectrum V.0, semi-automatically identifying regions of interest and displaying these regions to the user in the above mentioned views. The user can navigate both freely within the dataset/region of interest, or follow automatically computed paths to move through or move around the outside of the structure. Measurements of the viewed anatomical structure can be made.

The IMI Spectrum V.0 provides multi-dimensional visualization of digital images to aid clinicians in their analysis of anatomy and pathology. The IMI Spectrum V.0 user interface follows typical clinical workflow patterns to process, review, and analyze digital images, including:

- Select images for closer examination from a gallery of up to six 2D or 3D views
- Interactively manipulate an image in real-time to visualize anatomy and pathology
- Annotate, tag, measure, and record selected views

Intended Use

IMI Spectrum V.0 is a medical diagnostic system that allows the processing, review, and analysis of multi-dimensional digital images acquired from CT imaging devices. IMI Spectrum V.0 is not meant for primary image interpretation in mammography.

The IMI Spectrum V.0 is intended to receive patient specific data sets of CT images and can be used for:

- 3D presentation of complex anatomical relationships and specified structures within the complete data set;

- System generation of a 3D model of the desired anatomical structure;
- Viewing of the volume rendered and Multiplanar Reconstruction (MPR) representations of the desired anatomical structure providing additional supplemental information to support interpretation and treatment planning;
- Viewing the inner and outer surfaces of organs as well as within their walls providing additional supplemental information to support interpretation and treatment planning;
- Planning and following a navigation path through the desired anatomical structure;
- Programmed and interactive navigation and flythrough within the 3D volume including specified organs and structures;
- Measurement of position and length of anatomical structures within the 3D volume; and
- Common core technology with specialized interfaces for different anatomical structures.

Comparison to Predicate Device

The IMI Spectrum V.0 utilizes the same technological characteristic as the predicate device, Vitrea, Version 4.0 Medical Image Processing Software.

Both the IMI Spectrum V.0 and its predicate device provide multi-view user interfaces with combinations of 2D and 3D views correlated together for enhanced visualization. Both provide measurement tools for analysis of the observed structure, allow adjustment to virtual lighting parameters to emphasize details, and provide window/level adjustment of the 2D views to enhance features.

Discussion of Non-Clinical and Clinical Tests Performed for Determination of Substantial Equivalence

Testing was conducted using phantoms with structures of a known size and distance from the start inserted into the phantom. The person using the system did not have advance knowledge as to the number of structures nor their size or location. An independent reviewer then compared the test results with the actual phantoms and made an assessment as to accuracy.

The IMI Spectrum V.0 has been developed in a manner consistent with accepted standards for software development, including testing protocols. Testing on phantom objects has determined its level of accuracy, which is substantially equivalent to that of the predicate device. The product has shown itself to be reliable, easy to use, and capable of rendering useful 3D medical images.

IMI performed clinical tests on previously scanned, anonymized patient CT data to verify that the system/software performs as intended. Each patient data study was

assessed as to whether the core functionality of the system permitted flythrough and visualization. The clinical data was reviewed by a radiologist who determined that the rendering is accurate and medically useful.

IMI concludes from these tests that the Spectrum V.0 is substantially equivalent to the predicate device in its ability to render 3D images for use in medical diagnostics.

Performance Standards

The software designed to control and manipulate the diagnostic images follows the international standard CEI/IEC 62304:2006 Medical device software – Software life cycle processes. In accordance with that standard, the level of concern relative to this software has been determined as moderate using the decision tree provided in Version 1 of the FDA Software Guidance.

Summary of Studies

The software utilized was designed, developed, tested, and validated according to written procedures. These procedures specify individuals within the organization responsible for developing and approving product specifications, coding, testing, validating, and maintenance.

Conclusion

The IMI Spectrum V.0 has the same intended uses and similar technological characteristics as the Vitrea, Version 4.0 Medical Image Processing Software predicate device. Moreover, clinical and non-clinical testing demonstrated that the IMI Spectrum V.0 is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Intrinsic Medical Imaging
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MAY 31 2012

Re: K121023
Trade/Device Name: IMI Spectrum V.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 14, 2012
Received: May 15, 2012

Dear Mr. Goldner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE FORM

510(k) Number (if known): K121023

Device Name: IMI Spectrum V.0

Indications for Use:

The IMI Spectrum V.0 is a medical diagnostic system that allows the processing, review, and analysis of multi-dimensional digital images acquired from CT imaging devices. The IMI Spectrum V.0 is not meant for primary image interpretation in mammography.

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- Common core technology with specialized interfaces for different anatomical structures.

Prescription Use ☒ (21 CFR 801 Subpart D)	Or	Over-The-Counter Use ☐ (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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